



DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service  
Food and Drug Administration

9 20001

San Francisco District  
1431 Harbor Bay Parkway  
Alameda, CA 94502-7070  
Telephone: 510/337-6700

**VIA FEDERAL EXPRESS**

November 16, 2001

Our Reference: 2955797

Walter J. Guerra, President  
Italfoods, Inc.  
205 Shaw Road  
South San Francisco, California 94080

**WARNING LETTER**

Dear Mr. Guerra:

We inspected your seafood firm on October 2, 16, 17, 19, and 22, 2001. We conducted this inspection to determine your compliance with FDA's seafood processing regulations, 21 Code of Federal Regulations (21 CFR 123) and the Good Manufacturing Practice (GMP) requirements for foods (21 CFR 110).

We found that your firm has serious HACCP deficiencies. These deficiencies cause your canned or bottled Tuna in Oil and refrigerated vacuum packaged Smoked Salmon to be adulterated within the meaning of Section 402(a)(4) of the Federal Food, Drug, and Cosmetic Act (the Act), in that the fish have been prepared, packed, or held under insanitary conditions, whereby they may be rendered injurious to health. We listed the HACCP deficiencies on a Form FDA 483 and discussed them with you at the conclusion of the inspection. Your serious HACCP violations are as follows:

1. You must have product specifications that are designed to ensure that fish and fishery products you import are not injurious to health, to comply with 21 CFR

123.12(a)(2)(i). However, your firm does not have product specifications for the following:

- (a) Canned or bottled Tuna Packed in Oil (from [REDACTED] to ensure control of the food safety hazard of histamine formation as a result of time/temperature abuse of the product.
- (b) Refrigerated vacuum packaged Smoked Salmon (from [REDACTED]), to ensure control of the food safety hazard of pathogen growth and toxin formation, specifically *Clostridium botulinum* toxin, as a result of time/temperature abuse of the product.

2. You must implement an affirmative step, which ensures that the fish and fishery products you import are processed in accordance with the seafood HACCP regulation, to comply with 21 CFR 123.12(a)(2)(ii). However, your firm did not perform an affirmative step for:

- (a) Tuna Packed in Oil manufactured by [REDACTED] (shipped by [REDACTED] in [REDACTED])
- (b) Smoked Salmon manufactured by [REDACTED] in [REDACTED]

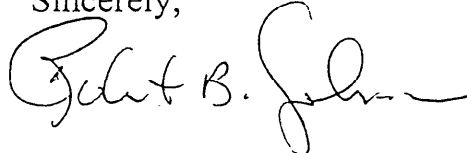
The above-identified deviations are not intended to be an inclusive list of deficiencies at your facility. It is your responsibility to ensure that all seafood products distributed by your firm are in compliance with the Federal Food, Drug, and Cosmetic Act and all requirements of the federal regulations.

You must immediately take appropriate steps to correct these deviations. We may initiate regulatory action without further notice if you do not correct the deviations. Regulatory action may include seizure and/or injunction. In addition, we may detain your imported seafood products without physical examination.

Please respond in writing within fifteen (15) working days of receipt of this letter. Your response should outline the specific things you are doing to correct these violations. Your response should include copies of any available documentation demonstrating that corrections have been made. If you cannot complete all the corrections before you respond, we expect that you will explain the reason for your delay and state when you will correct any remaining violations.

Please send your reply to the Food and Drug Administration, Attention: Erlinda N. Figueroa, Compliance Officer, 1431 Harbor Bay Parkway, Alameda, California 94502-7070. If you have questions regarding any issue in this letter, please contact Ms. Figueroa at (510) 337-6795.

Sincerely,

A handwritten signature in black ink, appearing to read "Robert B. Johnson", with a long horizontal flourish extending to the right.

Robert B. Johnson  
Acting District Director  
San Francisco District